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10/721,032	11/24/2003	James A. Goldstein	60018300-0010	4750

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SONNENSCHN NATH & ROSENTHAL LLP
P.O. BOX 061080
WACKER DRIVE STATION, SEARS TOWER
CHICAGO, IL 60606-1080

EXAMINER

JOHNSTON, PHILLIP A

ART UNIT PAPER NUMBER

2881

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/721,032

Applicant(s)

GOLDSTEIN, JAMES A.

Examiner

Phillip A. Johnston

Art Unit

2881

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-44 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-44 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Detailed Action

1. This Office Action is submitted in response to amendment dated 1-05-2005, wherein claim 45 is cancelled and claims 41 and 46 have been amended. Claims 21-44, and 46 are pending.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 21-46 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U. S. Patent No. 6,653,648, and claims 1-19 of U.S. Patent No. 6,448,571. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is obvious to one of ordinary skill in the art that all the limitations in Claims

21-46 of Application No. 10721032 are contained in Claims 1-20 of U. S. Patent No. 6,653,648, and claims 1-19 of U.S. Patent No. 6,448,571.

By way of example, a comparison of Claims 21-24 of Application No. 10721032, with Claim 1 of U. S. Patent No. 6,653,648, and claims 1 and 8 of U.S. Patent No. 6,448,571 is included below.

Claims 21-25 of Application No. 10721032, read as follows:

21. (Previously Presented) A method of performing a medical procedure, said method comprising: providing a radiation-shielding cubicle having an interior defining a medical personnel region and including a first wall having an opening therein; locating the cubicle with respect to an x-ray table so a portion of the x-ray table extends through the opening into the interior of the cubicle; and separating medical personnel from an x-ray emitter disposed outside of the cubicle using the first wall to shield the medical personnel from radiation emitted by the x-ray emitter.

22. (Previously Presented) A method in accordance with claim 21 further comprising joining the x-ray table to the cubicle using a radiation-shielding flexible interface.

23. (Previously Presented) A method in accordance with claim 22 wherein said joining the x-ray table to the cubicle using a radiation-shielding flexible interface comprises joining the x-ray table to the first wall using the radiation shielding flexible interface.

24. (Previously Presented) A method in accordance with claim 21 further comprising sealing the opening in the first wall using a flexible radiation-resistant skirt.

Claim 1 of U. S. Patent No. 6,653,648, read as follows;

Claim 1. A radiation protection system for shielding medical personnel from x-rays from an x-ray emitter while working on a patient, comprising:

an x-ray table having a first side, a second side and a top surface, the top surface for supporting a patient;

a radiation-shielding cubicle having an interior defining a medical personnel region, the cubicle having a ceiling, floor, a first wall for separating the medical personnel from an x-ray emitter disposed outside of the cubicle, a second wall extending from one end of said first wall adjacent to a first side of the x-ray table and a third wall extending from the first wall adjacent to a second side of the x-ray table, the first wall having an opening for locating a portion of the x-ray table into the interior of the cubicle;

a radiation-shielding screen attached to the x-ray table for covering the portions of the patient and the top surface of the x-ray table located in the interior of the cubicle;

a radiation-shielding flexible interface for joining the x-ray table to the cubicle, the flexible interface having a flexible radiation-resistant skirt sealing the opening; and an integrated procedural environment.

Claims 1 and 8 of U.S. Patent No. 6,448,571

Claim 1. A radiation protection system for shielding medical personnel from most radiation from an x-ray emitter and from x-ray scattering during radiologic procedures in which the medical personnel operate in close proximity to patient on an x-ray table, comprising:

a radiation-shielding wall separating the medical personnel from the x-ray emitter and having an opening around the x-ray table;

a radiation-shielding screen attached to the x-ray table and interposed between the patient and the medical personnel; and

a radiation-shielding flexible interface joining said wall with the x-ray table and said screen, said flexible interface having a flexible radiation-resistant skirt covering said opening in said wall.

Claim 8. A radiation protection system for shielding medical personnel from most radiation from an x-ray emitter and from x-ray scattering during radiologic procedures in which the medical personnel operate with surgical equipment in an operating region adjacent to a patient on an x-ray table, comprising:

a radiation-shielding cubicle surrounding the medical personnel in the operating region and extending over the x-ray table adjacent to the operating region,

said cubicle having a wall with an opening around the x-ray table;

a radiation-shielding screen attached to the x-ray table and interposed between the x-ray table and the medical personnel; and a radiation-shielding flexible interface circumferentially joining said cubicle with the x-ray table and said

screen, said flexible interface having a flexible radiation-resistant skirt covering said opening in said wall.

It is obvious to one of ordinary skill in the art that all the limitations in claims 21-24 of Application No. 10721032 are for the most part, contained in claim 1 of U.S. Patent No. 6,653,648, and Claims 1 and 8 of U. S. Patent No. 6,448,571.

Claims Rejection – 35 U.S.C. 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

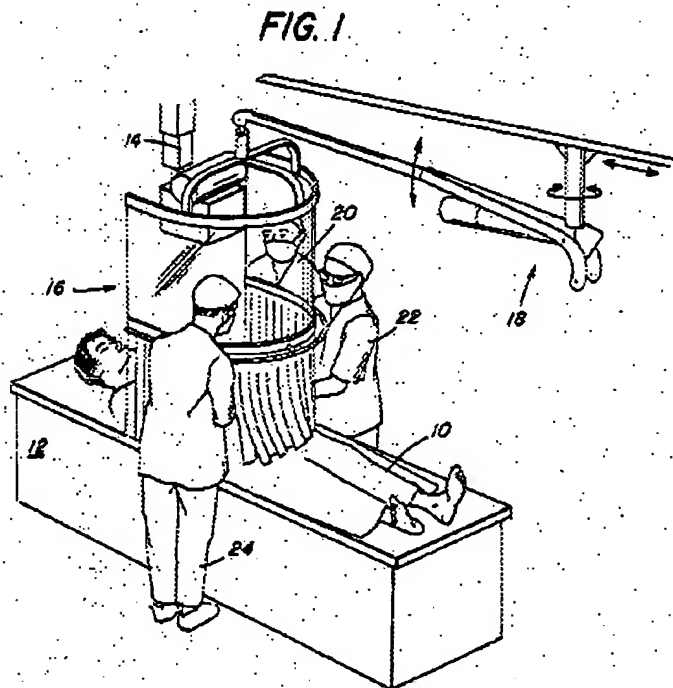
A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 34,37-42, 44, and 46 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,581,538, to Lenhart.

Lenhart (538) clearly discloses in FIG. 1, a special procedure room (the cubicle of claim 1 and 44) for angiographic examinations (the catheterization of claim 30), where patient 10 lying on table 12 is positioned with his torso in the line of X-rays delivered from conventional source 14. Shield 16, suspended from suspension system 18 is positioned to shield medical personnel 20, 22, 24 from X-rays traveling directly from source 14 or scattered from the air, from the patient, or from reflective surfaces in the vicinity of the work area. See Column 2, line 24-33; and Figure 1, below.

Lenhart (538) also discloses that, the flexibility of flaps 48 and 52 permits them to be draped (the flexible skirt of claims 22-27) over patient 10 and table 12 to form a continuous barrier (the wall and barrier of claims 21,39,41, and 42) to the penetration of X-rays beyond the work area thus shielding medical personnel 20, 22, 24. Several medical personnel at one time, can observe the patient, participate in a procedure, and move freely about the patient, with their entire bodies, including eyes, head and torso shielded from the X-rays. If it becomes necessary to touch the patient, a hand can easily be reached in between flaps 48, 52 (the ports of claims 28-30) without moving shield 16, and with minimum exposure to radiation. See Column 3, line 12-33.

Lenhart (538) further discloses the use of a video camera 68, as recited in claim 32. See Column 3, line 35-47.



Claims Rejection – 35 U.S.C. 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 35 and 36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,581,538, to Lenhart, in view of Heesch, U.S. Patent No. 6,325,538.

Regarding claims 35 and 36, Lenhart (538) as applied above fails to teach the use of a vascular access drape. However, Heesch (538) discloses that the waist collar 96 has to be quite flexible, and the entire lower portion of this part has to be covered in sterile sheets, in order to allow the operator to move the region of vascular access into the radiation field for x-ray guidance, should this become necessary due to access problems. See Column 11, line 19-54.

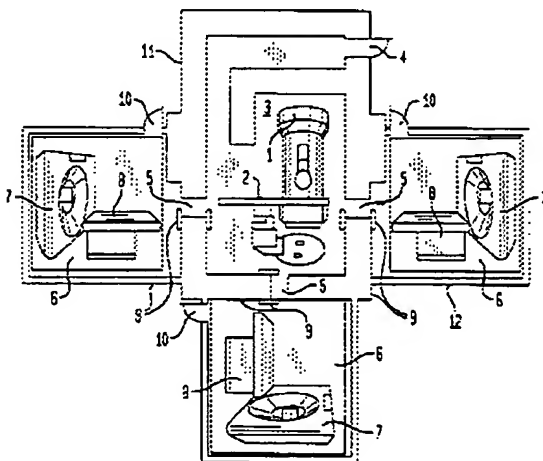
Therefore it would have been obvious to one of ordinary skill in the art that the radiation shield of Lenhart (538) can be modified to use the vascular access shield in accordance with Heesch (538), to move the region of vascular access into the radiation field for x-ray guidance.

8. Claim 43 stands rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,581,538, to Lenhart in view of Sahadevan, U.S. Patent No. 5,851,182.

Lenhart (538) fails to teach the use of a planar wall as a shield. However, Sahadevan (182) discloses the use of planar shielding walls 11 and 12 to separate a radiation therapy accelerator room from surrounding CT scan rooms, and openings 5 for the treatment table 2 to pass through. See Column 10, line 1-19; and Figure 1 below.

Therefore it would have been obvious to one of ordinary skill in the art that the radiation shield of Lenhart (538), can be modified to use the barrier wall of Sahadevan (182) to provide a dividing wall with an opening to allow communication between two treatment rooms.

FIG. 1



Examiners Response to Arguments

9. Applicant's arguments filed 1-05-2005 have been fully considered but they are not persuasive.

Argument 1

Regarding claims 21-33, and 40.

Applicant states that, " Lenhart does not disclose or suggest providing a radiation-shielding cubicle having an interior defining a medical personnel region, nor separating medical personnel from an x-ray emitter disposed outside of the cubicle."

The examiner agrees with the above argument, and will consider claims 21-33, and 40 allowed, following the timely filing of a terminal disclaimer to overcome the double patenting rejection above.

Argument 2

Regarding claims 34-39;

Applicant states that "Lenhart does not disclose or suggest inserting procedural equipment through a port to access a patient with the procedural equipment, nor performing a medical procedure on the patient using the procedural equipment. Rather, Lenhart discloses inserting a hand between flaps 48, 52 of a radiation-shielding curtain 40 to touch a patient, but does not disclose inserting procedural equipment through the flaps nor performing a medical procedure on the patient using the procedural equipment.

Because Lenhart does not disclose or suggest all of the elements of the claims, the Section 102 rejection of claims 34, 37, and 38 is improper and should be withdrawn."

The applicant also states that, " Claims 35 and 36 recite a method of using a radiation protection system including an x-ray table and a radiation-shielding screen that includes at least one port, wherein the method includes, among other things, inserting procedural equipment through the port to access the patient with the procedural equipment, and performing a medical procedure on the patient using the procedural equipment. As discussed above, Lenhart does not disclose or suggest inserting procedural equipment through the port to access the patient with the procedural equipment, nor performing a medical procedure on the patient using the procedural equipment. Heesch does not make up for the deficiencies in Lenhart. Because the cited references, considered alone or in combination, do not disclose or suggest all of the elements of claims 35 and 36, the Section 103 rejection is improper and should be withdrawn."

The applicant further states that, " Claim 39 recites a method of performing a medical procedure including, among other things, providing a radiation-shielding wall having an opening therein, and locating the wall with respect to an x-ray table so a portion of the x-ray table extends through the opening. As discussed above, Lenhart does not disclose or suggest providing a radiation-shielding wall having an opening therein, and locating the wall with respect to an x-ray table so a portion of the x-ray table extends through the opening. Because Lenhart does not disclose or suggest all

of the elements of the claim, the Section 102 rejection of claim 39 is improper and should be withdrawn."

The applicant is respectfully directed to Lenhart (538), Column 2, line 24-34, which states; Referring to FIG. 1(see above), in a special procedure room for angiographic examinations, patient 10 lying on table 12 is positioned with his torso (i.e., the work area, hidden in FIG. 1) in the line of X-rays delivered from conventional source 14. Shield 16, suspended from suspension system 18 (attached to the ceiling and shown out of scale in FIG. 1) is positioned to shield medical personnel 20, 22, 24 from X-rays traveling directly from source 14 or scattered from the air, from the patient, or from reflective surfaces in the vicinity of the work area.

The examiner has interpreted from Figure 1, and the references above that the Lenhart (538) invention is designed so that the patient is located on an x-ray table partially extending through the flaps of shield 16 to allow medical personnel to perform angiographic examinations on the patient while shielded from the x-ray machine. As a result, angiographic equipment is necessarily inserted through the flaps of shield 16 to perform the angiographic examination.

Argument 3

Regarding claims 41-44, and 46;

Applicant states that, " Claims 41, 42, and 44 recite a radiation protection system for shielding medical personnel from radiation emitted by an x-ray emitter during radiological procedures, wherein the system includes a table sized and shaped for supporting a patient, a radiation-shielding barrier, and a radiation shielding screen

connected to the barrier and attached to the table. Lenhart does not disclose or suggest a radiation protection system including a table sized and shaped for supporting a patient, a radiation-shielding barrier, and a radiation-shielding screen connected to the barrier and attached to the table."

Applicant also states that, " Claim 43 recites a radiation protection system for shielding medical personnel from radiation emitted by an x-ray emitter during radiological procedures, wherein the system includes a table sized and shaped for supporting a patient, a radiation-shielding barrier, and a radiation-shielding screen connected to the barrier and attached to the table. As discussed above, Lenhart does not disclose or suggest a radiation protection system including a table sized and shaped for supporting a patient, a radiation-shielding barrier, and a radiation-shielding screen connected to the barrier and attached to the table. Sahadevan does not make up for the deficiencies in Lenhart."

Applicant further states that, " Claim 46 recites a method for shielding medical personnel from radiation emitted by an x-ray emitter during radiological procedures including, among other things, shielding the medical personnel from x-ray radiation emitted from a patient by positioning a radiation-shielding screen between the medical personnel and the patient, and attaching the screen to a table for supporting the patient. As discussed above, Lenhart does not disclose or suggest attaching a radiation-shielding screen to a table for supporting the patient."

The applicant is respectfully directed to applicant's published specification in U.S. Patent Pub. No. 20040161076, Figure 1; and paragraph's [0027]-[0029], which state in

part; [0027] FIG. 1 illustrates a radiation protection system 10 that covers a patient 12 on an x-ray table 14 and separates an operating region 16 from a C-arm x-ray emitter 18. The radiation protection system 10 includes a radiation-shielding wall 20, a radiation-shielding screen 22 on the x-ray table, and a radiation-shielding flexible interface 24 connecting the screen 22 and x-ray table 14 with the wall 20.

[0028] The radiation-shielding screen 22 is movably attached to the x-ray table 14. The screen 22 may have a plurality of screen supports 34 (see also FIG. 6) attached to the x-ray table 14 and a radiation-resistant partition 36 attached to the supports 34. When extended, the screen 22 covers the x-ray table 14 in the personnel region 16 and the partition 36 is interposed between the patient 12 and the operators.

Thus, the connections between the screen 22, table 14, interface 24 and wall 20 (or cubicle 100 in other embodiments) creates a radiation-resistant seal.

[0029] The partition 36 may be formed from a flexible sheet of radiation-resistant material, permitting the screen 22 to fold like a curtain as the screen supports 34 slide along the table. It will be evident to those skilled in the art that other movable devices can be substituted for the sliding mechanism, including a screen that can rotate like an awning (not shown). Alternatively, the screen 22 may be constructed from rigid panels or segments. Also, screen segments may be hingedly attached like an accordion or rollably attached like a roll-top desk or a pool cover, or conformably attached like a Venetian blind.

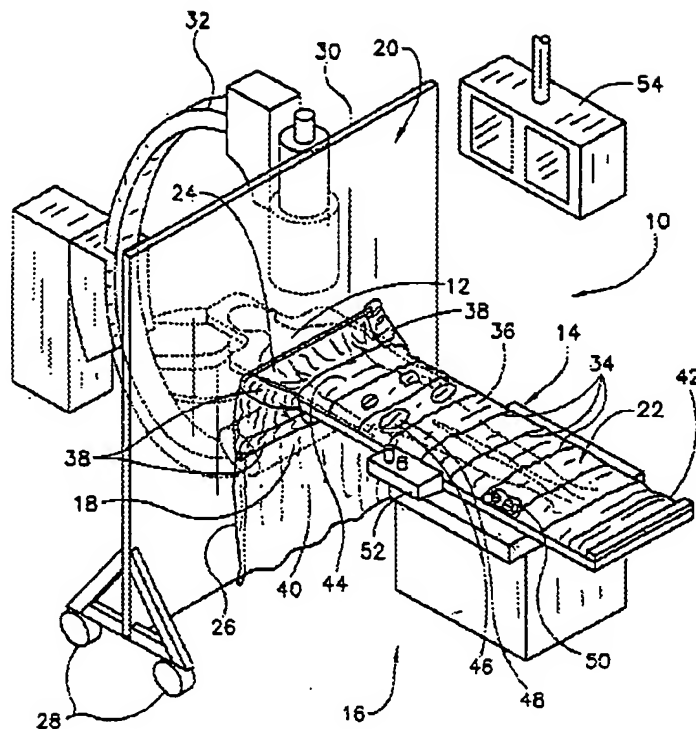
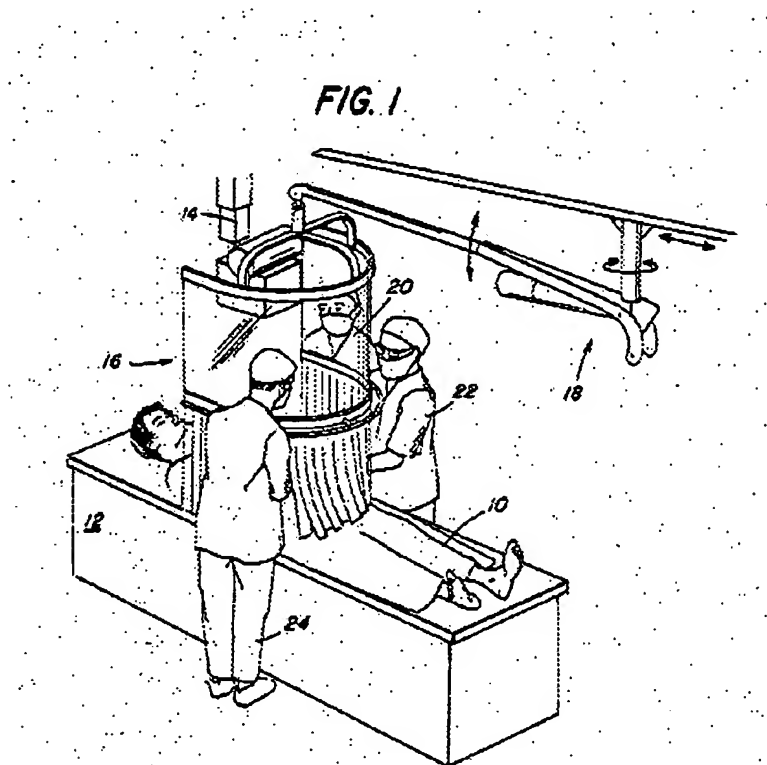


FIG. 1

The applicant is respectfully directed to Lenhart (538), Column 2, line 24-34, which states; Referring to FIG. 1 (below), in a special procedure room for angiographic examinations, patient 10 lying on table 12 is positioned with his torso (i.e., the work area, hidden in FIG. 1) in the line of X-rays delivered from conventional source 14. Shield 16, suspended from suspension system 18 (attached to the ceiling and shown out of scale in FIG. 1) is positioned to shield medical personnel 20, 22, 24 from X-rays traveling directly from source 14 or scattered from the air, from the patient, or from reflective surfaces in the vicinity of the work area.



The examiner has interpreted by comparing the applicant's Figure 1 with the Lenhart Figure 1, and the references above that the shielding curtain of Lenhart (538) is a flexible interface, which is attached to the x-ray table as claimed, in an equivalent manner to being movably attached, hingedly attached, rollably attached, and/or conformably attached, as described in the applicants references above.

Conclusion

10. The Amendment filed on 1-05-2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the Lenhart (538), Heesch (538), and Sahadevan (182) references.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications should be directed to Phillip Johnston whose telephone number is (571) 272-2475. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiners supervisor John Lee can be reached at (571) 272-2477. The fax phone number for the organization where the application or proceeding is assigned is 703 872 9306.

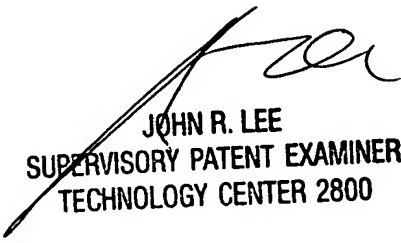
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic
Business Center (EBC) at 866-217-9197 (toll-free).

PJ
March 22, 2005



JOHN R. LEE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800